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K963288

510(K) SUMMARY

Device Sponsor: Li Medical, 4 Armstrong Road, Shelton, CT 06484,
203-944-2800

Contact: Rhodemann Li, Vice President

Date: October 30, 1996

Classification Name: Staple, Fixation, Bone

Common Name: Bone anchor

Proprietary Name: LM Anchor Products or other proprietary names

Predicate Devices: Mitek Surgical Products GII QuickAnchor (K904436)
Li Medical Bone Anchor (K951233), (K951472),
(K953764), (K960448), (K960439), (K960825)

Device Description: Made from surgical grade stainless steel (316L) or titanium
(6Al-4V ELI), the LM Anchor Products are designed with
a crown and a center pin through which suture is passed to
provide a means for soft tissue to bone attachment.

Intended Use:
(UltraFix RC,
UltraFix Mini,
UltraFix) Bladder neck suspension for female urinary incontinence
due to urethral hypermobility. Fixation in pubic bone for
the purpose of bladder neck suspension using USP #2 Class
I, non-absorbable, synthetic suture (e.g., polypropylene). A
minimum of two LM Anchors should be used in this
(modified MMK, Raz, or Stamey, i.e., Benderev)
procedure.

Technical Comparison: The LM Anchor Products are similar to the Mitek anchors
in its cylindrical shape, however, the bony purchase is
accomplished by the LM Anchor Products through
cantilevered beams versus nitinol arcs with the Mitek
anchors.

Performance Data: Pre-clinical testing in cadaver specimen showed that
the mean pullout strength of the LM Anchor Products were
substantially equivalent to the mean pullout strength of
the Mitek anchors